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Paper 208
Filed: 26 July 2010

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Administrative Patent Judge Sally Gardner Lane

Jean-Louis Ruelle
Junior Party
(Patent 6,780,419 and
Application 10/896,778),

v.

Vincenzo Scarlato, Vega Masignani, Rino Rappuoli,
Mariagrazia Pizza and Guido Grandi
Senior Party
(Application 11/212,443).

Patent Interference No. 105,551
Technology Center 1600

Before SALLY GARDNER LANE, RICHARD SCHAFER, AND MICHAEL P. TIERNEY, *Administrative Patent Judges.*

LANE, *Administrative Patent Judge*

Judgment– Merits – Bd. R. 127

A decision granting the Scarlato motion for priority and denying the Ruelle motion for priority has been entered. (Paper 207).

It is

ORDERED that judgment on priority as to Count 1 (Paper 1 at 4), the sole count of the interference, is entered against junior party Ruelle;

FURTHER ORDERED that claims 1-15 of Ruelle patent 6,780,419, which claims correspond to Count 1 (Paper 1 at 4), are CANCELLED, 35 USC 135(a):

FURTHER ORDERED that claims 1-14 of Ruelle application 10/896,778, which claims correspond to Count 1 (Paper 31 at 2), are FINALLY REFUSED, 35 USC 135(a):

FURTHER ORDERED that if there is a settlement agreement, the parties are directed to 35 USC 135(c) and Bd. R. 205; and

FURTHER ORDERED that a copy of this judgment shall be entered into the administrative record of the Ruelle involved patent and application and the Scarlato involved application.

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LANE, *Administrative Patent Judge*

Decision – Priority – Bd. R. 125(a)

I. Introduction

Each party has filed a motion for judgment based on priority. (Ruelle Priority Motion (Paper 130); Scarlato Priority Motion (Paper 135)). Oral argument on the motions was held 15 April 2010. Elliot Olstein appeared on behalf of junior party Ruelle. Matthew Kreeger appeared on behalf of senior party Scarlato. (Transcript (Paper 206)).

Because we determine that Scarlato was both the first to conceive and the first to reduce to practice an invention of the Count, we grant the Scarlato motion and deny the Ruelle motion.

II. Overview

The subject matter of the Count is an isolated protein from the B strain of *N. meningitis* (menB) or a fragment of that protein that would induce an immune response. The *N. meningitis* bacteria is the bacteria that causes bacterial meningitis.

Scarlato argues that it completed conception of the invention when inventor Dr. Vega Masignani identified the amino acid sequence for polypeptide gnmaa84r (also called ORF40[1]) while working at Chiron facilities in Emeryville, California. Ruelle argues that Scarlato did not conceive the invention because the "shotgun" sequences from The Institute of Genetic Research (TIGR) Dr. Masignani used to construct the gnmaa84r amino acid sequence were not reliable. Ruelle also argues that there is insufficient corroboration to establish a Scarlato conception.

III. Findings of fact

The record supports the following findings of fact, as well as any findings of fact

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[1] Our understanding is that Scarlato changed the name of the polypeptide (protein) over time. In this opinion, when we refer to either ORF40 or gnmaa84rr we are referring

set out elsewhere in the opinion, by a preponderance of the evidence.

The interference

1) The interference was declared on 11 June 2007 between junior party Ruelle and senior party Scarlato. (Declaration (Paper 1)).

2) Ruelle is involved on the basis of its 6,780,419 ('419) patent, issued 24 August 2004 from application 09/700,293, filed 13 November 2000 as well as its application 10/896,778, filed 22 July 2004. (Paper 1 and Redeclaration (Paper 31)).

3) Scarlato is involved on the basis of its application 11/212,443 ('443), filed 24 August 2005. (Paper 1).

4) Count 1, the sole count of the interference, is as follows:

Claim 1 of Ruelle [involved] patent '419

Or

Claim 18 of [involved] Scarlato application '443.

5) All of the claims of the involved patent and applications correspond to Count 1. (Paper 1 at 4 and Paper 31 at 2).

6) Claim 1 of Ruelle patent '419 recites:

An isolated polypeptide comprising a member selected from the group consisting of

(a) the amino acid sequence SEQ ID NO: 2;

(b) an immunogenic fragment of at least 15 contiguous amino acids of SEQ ID NO: 2;

wherein the immunogenic fragment, when administered to a subject in a suitable

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to the same polypeptide.

composition which can include an adjuvant, or a suitable carrier coupled to the polypeptide, induces an antibody or T-cell mediated immune response that recognizes the isolated polypeptide SEQ ID NO: 2.
(Paper 7).

7) Claim 18 of the Scarlato application '443 recites:

An isolated polypeptide comprising a member selected from the group consisting of

(a) the amino acid sequence of SEQ ID NO: 4; and

(b) an immunogenic fragment of at least 15 contiguous amino acids of SEQ ID NO: 4,

wherein the immunogenic fragment, when administered to a subject in a suitable composition which can include an adjuvant, or a suitable carrier coupled to the polypeptide induces an antibody or T-cell mediated immune response that recognizes a polypeptide of the amino acid sequence as set forth in SEQ ID NO: 4.
(Paper 11).

8) For purposes of priority, Ruelle was accorded benefit of application PCT/EP99/03255, filed 7 May 1999 (Paper 28 at 2) and Great Britain application 98/10276), filed 13 May 1998 (Paper 128 (Redeclaration) at 2).

9) For purposes of priority, Scarlato was accorded benefit of US applications 10/695,499 filed 28 October 2003 and 09/302,626 filed 30 April 1999 (Paper 1 at 4), as well as the following non US applications:

Great Britain application 98/00760, filed 14 January 1998 ("GB '760");
Great Britain application 98/19015, filed 1 September 1998;
Great Britain application 98/22143, filed 9 October 1998;
PCT application PCT/IB99/00103, filed 14 January 1999; and
(Paper 128 at 2).

10) The real-party-in-interest for Ruelle is GlaxoSmithKline Biologicals S.A. (Notice of

real-party-in-interest (Paper 5)).

11) The real-party-in-interest for Scarlato is Novartis Vaccines and Diagnostics SRL. (Notice of real-party-in-interest (Paper 10)).

The priority statements

12) Each party filed a priority statement.

13) In its statement, Ruelle alleged an earliest conception date of 6 October 1997 and an earliest actual reduction to practice date of 16 January 1998. (Priority Statement (Paper 41)).

14) The Ruelle motion seeking to amend its priority statement to allege an earlier reduction to practice date was denied. (Decision on Motion (Paper 129 at 2)).

15) In its statement, Scarlato alleged an earliest conception date of 13 August 1997. (Priority statement (Paper 43)).

The Scarlato conception

16) Scarlato presented the testimony of inventor Dr. Rino Rappuoli (Rappuoli Declaration (Ex. 1102), inventor Dr. Vega Masignani (Masignani Declaration (Ex.1104), Dr. David Kingsbury (Kingsbury Declaration (Ex.1107) and Dr. David Pot (Pot Supplemental Declaration) Ex.1112)).

17) Dr. Rappuoli is the Global Head of Vaccines Research at Novartis Vaccines and Diagnostics ("Novartis", formerly Chiron SRL ("Chiron")). (Ex. 1102 at ¶¶1-3).

18) From 1996-2000, Dr. Rappuoli was Vice President of Vaccines Research at Chiron, during which time her split his time between Chiron facilities in Emeryville, California and Chiron facilities in Siena, Italy. Ex. 1102 at ¶¶1-3).

19) Dr. Vega Masignani is a Project Leader for the *Streptococcus pneumoniae*

vaccine project at Novartis in Siena, Italy. (Ex.1104 at ¶ 1).

20) During the relevant time frame, Dr. Masignani was a doctoral student in Biotechnology and was working with the vaccinology group at Chiron in Siena. (Ex.1104 at ¶ 2).

21) During the relevant time from Dr. David Kingsbury was Vice President and Chief Information Officer at Chiron in Emeryville, California (Ex.1107 at ¶ 1).

22) During the relevant time frame Dr. David Pot was Senior Applications Bioinformaticist in the Bioinformatics Department at Chiron in Emeryville. (Ex. 1112 at ¶ 1).

Dr. Rappuoli

23) Dr. Rappuoli testified that in late 1996 he began to think of using the bacterial pathogen menB for vaccine or diagnostic purposes. (Ex. 1102 at ¶ 4).

24) Dr. Rappuoli testified that he had the idea to sequence the genome of the pathogen and then to analyze the sequence to identify potential antigens which could then be cloned, expressed, and tested for immune response. (Ex. 1102 at ¶ 9).

25) Dr. Rappuoli testified that, due to the large number of open reading frames[2] a pathogenic bacterium typically contains (i.e., two to five thousand), he and the other Scarlato inventors had a plan to use a computer-based sequence analysis program to initially screen menB open reading frames to identify antigen candidates for further study. (Ex. 1102 at ¶ 11).

[2] We understand an open reading frame to be a DNA sequence that potentially could code a protein because it lacks stop codons.

26) According to Dr. Rappuoli the plan was to identify candidate antigens meeting the following criteria:

(a) Homology to a protein that is surface exposed, secreted from the cell or known to be involved in virulence in the organism;

(b) A region or motif indicating the presence of a transmembrane region; and

(c) A "signal sequence" motif indicating that the protein may be secreted from the cell or anchored to the outer membrane through lipidation.

(Ex. 1102 at ¶ 11).

27) Dr. Rappuoli testified that the computer facilities where he was working in Italy did not have sufficient power to perform the needed sequence analysis so he approached colleagues at Chiron in Emeryville to ask for assistance. (Ex.1102 at ¶ 12).

28) Dr. Rappuoli testified that, over the course of several meetings, he discussed the plan to identify candidate proteins with (non-inventor) Dr. David Kingsbury, who was Vice-President and Chief Information Officer at Chiron in Emeryville. (Ex. 1102 at ¶¶ 13-17).

29) The plan was to start with the genome of menB, identify all of the open reading frames in that genome, and then to express and screen all of the open reading frames at both the DNA and protein level to identify potential antigens based on the outlined criteria. (Ex.1102 at ¶ 13; Ex.1107 at ¶¶ 15-16).

30) Dr. Rappuoli explained to Dr. Kingsbury the idea that proteins or fragments of such proteins meeting the outlined criteria would likely induce an antibody or T-cell mediated response that recognizes the full length native protein when

administered to a subject, i.e., act as antigens. (Ex.1102 at ¶ 13; Ex.1107 at ¶ 8).

31) Dr. Rappuoli further explained that the antigen candidates could then be characterized for suitability for use in a vaccine effective against multiple menB strains using conventional techniques. (Ex.1102 at ¶ 13; Ex.1107 at ¶ 8).

32) Dr. Rappuoli testified that in early 1997 he and the other inventors learned that The Institute for Genomic Research (TIGR) was working on sequencing the menB genome via the "shotgun method".[3] (Ex.1102 at ¶ 18, Ex.1104 at ¶ 7; Ex.1107 at ¶ 15).

33) Dr. Rappuoli testified that in July 1997, he and the other inventors learned that The Institute for Genomic Research (TIGR) had uploaded the reads it had obtained from partially sequencing the menB genome. (Ex.1102 at ¶ 18, Ex.1104 at ¶ 7, Ex.1107 at ¶ 15).

34) Dr. Rappuoli testified that once the menB genome had been partially sequenced by TIGR, he asked inventor Dr. Vega Masignani (who at that time was a doctoral student) to go to Chiron facilities in Emeryville to analyze the menB sequence using the plan he had discussed with Dr. Kingsbury and the other inventors. (Ex. 1102 at ¶ 18; Ex.1107 at ¶ 15).

35) Dr. Kingsbury and Dr. Masignani each provided testimony that is consistent with the testimony of Dr. Rappuoli. (Ex. 1107 at ¶¶ 5-11, 14 and 15; Ex. 1104 at ¶¶ 4-8).

[3] We understand that in shotgun sequencing, DNA is broken up into random fragments which are then sequenced to obtain "reads". (Ex. 1102 at ¶ 15).

Dr. Masignani

36) Dr. Masignani testified that, on 4 August 1997 after her arrival in Emeryville, she met with Dr. Kingsbury and discussed the plan developed by the inventors for identifying candidate proteins. (Ex. 1104 at ¶ 9; Ex.1107 at ¶¶ 16-17).

37) Dr. Masignani testified that she worked on a computer outside Dr. Kingsbury's office while she was at the Emeryville facilities. (Ex. 1104 at ¶ 11; Ex.1107 at ¶ 21).

38) Dr. Kingsbury provided testimony that is consistent with the testimony of Dr. Masignani. (1107 at ¶¶ 15-17, 21; see also Ex.1109[4] and Ex.1111[5]).

39) Dr. Masignani testified that after her arrival in Emeryville she also met with Dr. David Pot, a senior applications bioinformatics for Chiron in Emeryville and told him of the plan for identifying candidate proteins. (Ex. 1102 at ¶¶ 10-11and Ex. 1112 (Pot Declaration) at ¶¶ 1-2 and 10).

40) Dr. Masignani testified that Dr. Pot trained her on the appropriate computer system at Chiron in Emeryville and helped her install the partial menB genome into the UNIX computer system she would be using there. (Ex. 1102 at ¶ 11 and Ex. 1112 at ¶ 12).

41) Part of that training involved the use of FASTA, a known software package that performs protein and DNA sequence alignments using an algorithm that

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[4] Exhibit 1109 appears to be an e-mail from Dr. Kingsbury to "Tony", said to be Anthony Kerlavage at TIGR, that mentions work with menB by a visiting graduate student from Siena, Italy.

[5] Exhibit 1111 appears to be an e-mail dated 6 August 1997 from Dr. Pot discussing that Dr. Masignani would be analyzing the menB partial genome for comparison with known sequences.

compares a protein (or DNA) sequence to another protein (or DNA) sequence or database of sequences. (Ex.1104 at ¶10, Ex.1112 at ¶ 11, Ex.1107 at ¶ 20, Scarlato Statement of Material Fact (SMF) 45 (admitted by Ruelle (Ruelle Opposition (Paper 139)).

42) Dr. Masignani's testimony indicates that she had used FASTA and only needed to be familiarized with the specific computers she would be using at Emeryville. (Ex.1104 at ¶ 10, Ex.1112 at ¶ 13, Ex.1107 at ¶18 and Ex.1106, Scarlato SMF 48 (admitted by Ruelle (Paper 139)).

43) Dr. Pot's testimony regarding the training he provided to Dr. Masignani is consistent with her testimony. (Ex. 1112 at ¶ 9-29; see also Exs. 1110[7] and 1111).

44) Dr. Masignani testified that once the partial menB DNA fragments from TIGR were placed on Chiron's internal computer system, she used a computer program to translate all six reading frames for each DNA fragment (which we understand as three from each strand of DNA) into the corresponding amino acid sequences. (Ex. 1104 at ¶12).

45) Dr. Masignani testified that she selected the longest amino acid sequence (corresponding to the longest open reading frame) for each of the DNA fragments and then compared each one to Chiron's internal database of known proteins. (Ex. 1104 at ¶ 12).

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[6] Ex.1110 appears to be an e-mail dated 6 August 1997 from Dr. Pot to regarding the bioinformatics resources that Dr. Masignani would need while at Emeryville.

[7] Ex. 1111 appears to be an e-mail from Dr. Pot discussing computer training for Dr. Masignani.

46) Dr. Masignani testified that as a result of this initial screening, she identified two overlapping amino acid sequences having homology to an amino acid sequence for the type b surface fibril *Haemophilus influenza*e protein (Hsf), a known adhesion protein. (Ex. 1104 at ¶ 13).

47) Dr. Masignani testified that she knew that adhesion proteins were desirable vaccine candidates because they play an essential role in infection and are located at the surface of the bacteria making them accessible to antibodies. (Ex.1104 at ¶ 14).

48) Dr. Masignani testified that she then combined the nucleic acid sequences corresponding to the two overlapping amino acid sequences, gnmaa71r and gnmaa84, to form a single overlapping nucleic acid sequence and called this nucleic acid sequence open reading frame 40, or "ORF40." (Ex. 1104 at ¶12).

49) Dr. Masignani testified that she subsequently saved the ORF40 sequence to her subdirectory on the Chiron computer network to a file which she named "gnmaa84r." (Ex. 1104 at ¶12).

50) Dr. Masignani testified that on 13 August 1997 she compared the amino acid sequence translated from the ORF40 sequence, the gnmaa84r polypeptide, with Chiron's internal database of known proteins using a FASTA sequence comparison program in order to confirm the homology of the gnmaa84r sequence to Hsf. (Ex. 1104 at ¶13).

51) Dr. Masignani testified that the comparison showed that "ORF 40" (gnamaa84r) has a 57.4% homology to Hsf. (Ex. 1104 at ¶ 13).

52) Dr. Masignani testified that she realized at the time that at least amino acids 13-

69 and 71-244 of gnmaa84r each constituted a fragment of the full-length native menB protein that would be capable of eliciting an immune response to that protein. (Exh.1104 at ¶ 14; Ex.1118 (Kelsoe Declaration) at ¶12).

53) Dr. Masignani testified that the comparison of gnmass84r with the Hsf protein is reflected in a printout dated 13 August 1997. (Ex. 1104 at ¶ 13 referring to Ex. 1106).

54) The printout states that it is a "FASTA of: gnmass84r.pep", and indicates that "the best scores are" the 57.4% homology between the gnmaa84r and the Hsf protein. (Ex. 1106; (Ex. 1112 at ¶¶ 15-29).

55) Dr. Pot testified that he created a subdirectory "vega," to his UNIX account, "potd," where Dr. Masignani could store files relating to her sequence analysis work and trained her in printing out the results of her sequencing analysis work, including how to print out results from the FASTA Program . (Ex.1112 at ¶¶11-12, Ex. 1104 at ¶ 11.)

56) Dr. Pot testified that he was very familiar with the types of printouts that the Chiron bioinformatics systems generated in 1997, including printouts from the FASTA program. (Ex.1112 at ¶ 12).

57) Dr. Pot testified that while he did not recall seeing Exhibit 1106 in particular, he recognized it as being generated by the FASTA program at Chiron that was in place on 13 August 1997. (Ex. 1112 at ¶16).

58) Dr. Pot testified that in line 11 of Exhibit 1106, the phrase "/z3/u1/potd/vega/GNMAA/hsf.haein" is the UNIX path to the directory that he set up for Dr. Masignani under his UNIX account "potd" and that the reference

"hsf.haein" having the GenInfo Identifier number "gi|1666683" that corresponds to a protein encoded by the type b surface fibril *Haemophilus influenzae* . (Ex.1112 at ¶ 22).

59) Dr. Pot testified that the printout reflects a comparison of gnamaa84r with Hsf and shows a homology score of 57.4%. (Ex. 1112 at ¶ ¶ 15-29).

60) Dr. Masignani testified that while she was still in Emeryville she discussed the gnmaa84r polypeptide with Dr. Rappuoli and he agreed that the polypeptide would be one of the best antigen candidates given its homology to the Hsf protein. (Ex.1104 at ¶ 15 and Ex.1102 at ¶ 19).

61) Dr. Kingsbury testified that, prior to leaving Emeryville in early September of 1997, Dr. Masignani told him that based on her sequence analysis of the partial menB genome she had obtained several good leads for vaccine candidates for menB. ((Ex. 1107 at ¶ 22).

62) Neither Dr. Kingsbury, Dr. Pot, nor any other non-inventor, saw Exhibit 1106 while Dr. Masignani was in Emeryville.(Ruelle SMFs185,187, and 188, admitted by Scarlato).

63). Prior to filing the GB '760 application on 14 January 1998, Dr. Masignani worked with Dr. Scarlato to prepare final alignments by reviewing the alignments and translating open reading frames by hand to identify likely sequence errors. (Ex.1007; Ex.1104 at ¶18; Ex.1102 at ¶ 21).

64) Dr. Masignani discovered that there had been a frameshift error that was corrected by deleting a single nucleotide from the DNA sequence of gnmaa84r (ORF40). (GB '760 application (Ex.1007; Ex.1104 at ¶ 18; Ex.1102 at ¶ 21).

Dr. Kelsoe

65) Scarlato provides the testimony of Dr. Garnett H. Kelsoe. (Ex. 1118).

66) Dr. Kelsoe is a professor of immunology at Duke University Medical Center and has an extensive list of publications and other activities in the field of immunology. (Ex. 1002 (curriculum vitae)).

67) We find Dr. Kelsoe to be well qualified to testify about the subject matter of this interference.

68) Dr. Kelsoe testified, and it is apparent, that amino acids 13-69 and 71-244 of gnmaa84r are identical to amino acids 53-109 and 111-284 of SEQ ID NO:4 of Scarlato's involved '443 application. (Ex. 1118 at ¶ 14 referring to sequence alignment at Ex 1114).

69) Dr. Kelsoe testified that one skilled in the art would be virtually certain that the gnmaa84r polypeptide would be an immunogenic fragment within the scope of the Count, i.e., that it is a fragment of at least 15 contiguous amino acids that would elicit an antibody or T-cell mediated response that recognizes the native menB protein defined at Scarlato SEQ ID NO: 4. (Ex. 1118 at ¶12-15).

Dr. Dyer

70) Dr. David Dyer is a professor of Microbiology and Immunology at the Oklahoma University Health Sciences Center and has conducted research and published in the field of immunology. (Dyer curriculum vitae (Ex. 2078)).

71) We find Dr. Dyer to be well qualified to testify about the subject matter of this interference.

72) Dr. Dyer testified that that there were not enough DNA fragments in the TIGR

database in August 1997 to allow one to be certain that the 71r and 84r overlapping fragments[8] had been assembled properly into an extended DNA fragment present in the menB genome that encoded the gnmaa84r polypeptide. (Dyer Declaration (Ex. 2077) at ¶ 25, 31-38, 40-43, 47,and 48).

73) Dr. Dyer testified that it was equally likely that the DNA had been extended improperly because of a mistake in sequencing in TIGR or homology within different genes within the menB genome. (Ex. 2077 at ¶ 25, 31-38, 47,and 48).

IV. Discussion

In an interference contest, priority of invention generally goes to the party that was the first to reduce the invention to practice unless another party can show that it had a prior conception of the invention and then exercised reasonable diligence. 35 USC §102(g).

Based on the grant of its benefit motion (Decision on Motions (Paper 107) at 32), Scarlato was the first to reduce the invention to practice. Ruelle has not alleged, and thus cannot show, a reduction to practice that is earlier than the Scarlato reduction to practice. Bd. R. 204(a).

In its priority motion, Scarlato argues that it also was the first to conceive the invention, i.e., that it conceived an invention of the Count on 13 August 1997, prior to Ruelle's earliest alleged conception date of 6 October 1997. (Paper 41 at 2).

Scarlato Conception

Conception is the formation, in the mind of the inventor, of a definite and

[8] We understand Dr. Dyer to be referring to the two overlapping amino acid sequences, the DNA of which was combined by Dr. Masignani to arrive at ORF40.

permanent idea of the complete and operative invention, as it is later applied in practice. *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir.1998). Conception cannot be "accidental" since the inventor must appreciate that which has been invented in order to have conceived of it. *Invitrogen Corp. v Clontech Lab., Inc.* 429 F.3d 1052, 1063 (Fed. Cir. 2005).("In other words, conception requires that the inventor appreciate that which he has invented."); *Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1341 (Fed. Cir. 2001) ("[T]he date of conception of a prior inventor's invention is the date the inventor first appreciated the fact of what he made.")

Conception requires that the inventor be able "to describe his invention with particularity" but does not require that the inventor know that his invention will work since discovery that an invention actually works is part of its reduction to practice. *Burroughs Wellcome Co. v. Barr Labs. Inc.*, 40 F.3d 1223, 1228 (citing *Applegate v. Scherer*, 332 F.2d 571, 573 (CCPA 1964)).

There is no dispute that the gnmass84r protein identified by Dr. Masignani on 13 August 1997 is an immunogenic fragment of at least 15 contiguous amino acids of SEQ ID NO: 4 and therefore an embodiment of the Count. (Scarlato SMF 78, admitted by Ruelle (Paper 139) and Scarlato SMF 80, admitted in part by Ruelle (Paper 139)). Ruelle concedes that it was not necessary for Scarlato to show that the gnmaa84r polypeptide was operative as a vaccine or diagnostic for conception to have occurred (Ruelle Opposition (Paper 139) at 5). Instead Ruelle argues that Scarlato could not have had a "definite and permanent idea" of the invention because Scarlato did not have sufficient basis for believing that the polypeptide sequence it identified actually

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(Ex. 1104 at ¶ 12).

was from native *menB*. (Paper 139 at 6).

Ruelle relies upon the testimony of Dr. Dyer that the partial sequences Scarlato obtained from TIGR could have contained sequencing errors and that the two sequences overlaid by Dr. Masignani might have been from different, but homologous, genes. Dr. Dyer opined that it was "equally plausible" that the gnmaa84r was not from native menB. (Ex. 2077 at ¶¶ 25, 31-38, 47 and 48). In short, Dr. Dyer testified that one skilled in the art could not have been certain that the polypeptide gnmaa84r was from menB.

We are not persuaded, in the circumstances before us, that it was necessary for Scarlato to have been certain that gnmaa84r was from native *menB* for conception to have been complete. Conception is the formation of an idea, not confirmation that the idea is correct. We agree with Scarlato that "demonstrating that the idea was correct is part of reduction to practice, not conception." (Scarlato Reply 2, Paper 144 at 3). *See Burroughs* at 1228 ("But an inventor need not know that his invention will work for conception to be complete.... He need only show that he had the idea; the discovery that an invention actually works is part of its reduction to practice.") (citations omitted). Scarlato had a "specific, settled idea" and not just a "general plan" lacking sufficient detail to allow one to "understand the invention". *Id.* Scarlato's conception included identification of an amino acid sequence of an immunogenic fragment within the Count, not merely identification of a utility that it hoped to obtain. *Cf. Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir 1993), A*mgen v. Chugai Pharmaceuticals, Ltd.*, 927 F.2d 1200, 1206 (Fed. Cir 1991).

Thus even accepting Dr. Dyer's testimony that it was "equally plausible" that

gnmass84r was not present in the menB genome, we conclude that Scarlato had a definite and permanent idea of the invention when it identified the gnmass84r polypeptide by its amino acid sequence (Ex. 1106). While "wet work" might have been required for a reduction to practice (Ruelle Opposition Paper 139 at 13), it was not required for conception in the circumstances before us where the inventors identified the structure, i.e., the amino acid sequence, of the invention.

Correction of sequence

Ruelle argues that the deletion of a single nucleotide from SEQ ID NO. 4 prior to filing the GB '760 application establishes that the Scarlato inventors did not have a definite and permanent idea of the invention. (See Ex. 1115, comparing gnmaa84r to SEQ ID NO:4 of GB '760). We disagree.

The Count requires only an immunogenic fragment of at least 15 contiguous amino acids of SEQ ID NO. 4. Even without the single nucleotide correction the gnmaa84 polypeptide is within the Count. (See Ex. 1114; comparing gnmaa84r to SEQ ID NO:4 of the '443 involved application). It has held that "conception is not complete if the subsequent course of experimentation, especially experimental failures, reveals uncertainty that so undermines the specificity of the inventor's idea that it is not yet a definite and permanent reflect of the complete idea as it will be used in practice." *Burroughs* at 1229. However, the one nucleotide correction by Scarlato does not rise to a level sufficient to undermine the completeness of its conception. Instead, the inventor's explanation that upon preparing final alignments a frame shift error was detected and corrected is reasonable and, as noted above, the correction did not negate the fact that gnmaa84r is an invention of the Count.

Ruelle also points to a series of X's that are shown for amino acid residues 38 to 49 and 156 to 167 in the overlap of the putative "ORF40" polypeptide with Hsf protein in the GB '760 application. (Ex. 2077 at ¶ 56). The Count requires only an immunogenic fragment of at least 15 contiguous amino acids of SEQ ID NO. 4. Even with insertion of Xs for certain amino acids, the gnmaa84 polypeptide disclosed in GB '760 is within the Count. (See Ex. 1114; comparing gnmaa84r to SEQ ID NO:4 of the '443 involved application). Thus, these X's do not negate that gnmaa84r is an invention of the Count. Moreover, Ruelle has not explained how the presence of the X's shows a degree of uncertainty sufficient to undermine the completeness of the conception. As noted by Ruelle, Dr. Rappuoli testified that the X's were inserted in order to analyze homologies for the ORF40 amino acid sequence to the Hsf protein. (Paper 139 at 18). We find Dr. Rappuoli's testimony on this point to be credible when viewed in light of the other evidence before us.

Corroboration

Corroboration of the inventor's belief is necessary to establish conception. In particular, the fact that the inventor appreciated the features of the invention must be corroborated with objective evidence. *Invitrogen* at 1065. The requirement for corroboration of an inventor's testimony stems from the concern that a party claiming inventorship might be tempted to describe his actions in an unjustifiably self-serving manner in order to obtain a patent or to maintain an existing patent. *Chen v. Bouchard,* 347 F.3d 1299, 1309 (Fed. Cir. 2003). However, "[t]here is no final single formula that must be followed in proving corroboration." *Berry v. Webb*, 412 F.2d 261, 266, (CCPA 1969) (citation omitted). Instead, whether an inventor's testimony is corroborated

sufficiently should be evaluated using a "rule of reason." "An evaluation of all pertinent evidence must be undertaken so that a sound determination of the credibility of an inventor's story can be made." *Price v. Symsek*, 988 F.2d 1187, 1195 (Fed. Cir. 1993). For example, "circumstantial evidence of an independent nature may satisfy the corroboration requirement." *Cooper*, 154 F.3d at 1330 (citation omitted). "In the final analysis, each corroboration case must be decided on its own facts with a view to deciding whether the evidence as a whole is persuasive." *Berges v. Gottstein,* 618 F.2d 771, 776 (CCPA 1980).

Dr. Masignani testified that she identified gnmaa84 on 13 August 1997 and that she realized at that time that it was an immunogenic fragment of a menB protein. (Ex. 1104 at ¶ 14). In support of this testimony Scarlato relies upon, *inter alia*, Exhibit 1106, said to be a FASTA print out showing a sequence comparison of the gnmaa84 and the Hsf amino acid sequence.

Ruelle argues that Exhibit 1106 is not sufficient on its face to corroborate Dr. Masignani's testimony. Ruelle contends that Scarlato has not provided evidence to show that Exhibit 1106 (or any other indication of the gnmass84r sequence) was shown to a non-inventor during the relevant time frame or that Exhibit 1106 even existed on 13 August 1997. (Paper 139 at 19). Moreover, Ruelle argues that the exhibit does not establish the date on which Dr. Masignani first had knowledge of the sequence of the gnmaa84r polypeptide. (Paper 139 at 24).

We apply a rule of reason analysis and consider the evidence as a whole in deciding whether there is sufficient corroboration of the Scarlato conception. In the present circumstances, the evidence establishes that Dr. Rappuoli and Dr. Masignani

explained the plan to use partial menB sequences from TIGR to identify menB antigen candidates to Dr. Kingsbury (Ex. 1107 at ¶¶ 8, 16, and 17) and Dr. Masignani to Dr. Pot as well (Ex. 1112 at ¶¶ 1 and 10). The evidence further establishes that Dr. Pot assisted Dr. Masignani in placing the TIGR menB partial sequences on the computer system in Emeryville and that he set up a particular subdirectory where Dr. Masignani could save her work. Dr. Pot testified that he was familiar with printouts generated by Chiron's FASTA program and that he recognized Exhibit 1106 to be a printout generated by that program from 13 August 1997. Dr. Pot further testified that the printout showed that the comparison between gnmaa84r and Hsf has been completed on 13 August 1997 (Ex. 1112 at ¶ 16) and showed a path to the subdirectory that Dr. Pot had created for Dr. Masignani to store her work. (Ex. 1112 at ¶ 22).

Dr. Kingsbury testified that he was aware that Dr. Masignani was working on sequence analysis program to analyze partial menB sequences from TIGR. (Ex. 1107 at ¶ 21). Dr. Kingsbury further testified that prior to her return to Italy, Dr. Masignani informed Dr. Kingsbury that based on her sequence analysis of the partial menB genome, she had obtained several good leads for vaccine candidates for menB. (Ex. 1107 at ¶22).

We conclude that the Scarlato conception, and in particular the testimony of Dr. Masignani, is sufficiently corroborated under the rule of reason. The non-inventor testimony, in combination with the documentary evidence provided at Exhibit 1106 when viewed in light of that testimony, supports Dr. Masignani's testimony that she identified gnmaa84 on 13 August 1997. While the evidence establishes that neither Dr. Kingsbury nor Dr. Pot saw Exhibit 1106 while Dr. Masignani was in Emeryville, Dr. Pot

testified that he recognized the Exhibit as a print out from Chiron's FASTA program of data generated on 13 August 1997. Dr. Masignani testified that she viewed that data on 13 August 1997 "immediately" realizing at that time that gnmaa84r was an immunogenic fragment of a menB protein. (Ex. 1104 at ¶ 14). That testimony is supported by Dr. Kingsbury's testimony that Dr. Masignani told him that based on her sequence analysis of the partial menB genome she had obtained several good leads for vaccine candidates for menB. (Ex. 1107 at ¶ 22).

Finally we are not persuaded that Dr. Masignani's failure to recall certain details of the work she performed in Emeryville or to produce notebook pages shows that her testimony is "unreliable to establish invention acts." (Paper 139 at 27-28 citing to *Kridl v. McCormick,* 105 F.3d, 1446, 1450 (Fed. Cir. 1996). It is understandable that a witness might not recall or have extensive records reflecting each detail of work performed over ten years ago. Ruelle has not shown that the details forgotten by Dr. Ruelle are so significant, or the production of notebook pages so critical, that we could not conclude that conception had occurred on the basis of the other evidence before us.

Because we conclude that Scarlato was the first to conceive and reduce to practice an invention of the Count, we GRANT the Scarlato Motion.

The Ruelle Motion for Priority

In its Opposition, Ruelle presents arguments that it is entitled to judgment on priority because Scarlato is not entitled to priority benefit of the GB '706 application. (Paper 139 at 28-30). Scarlato's motion for benefit of the GB '760 application was granted (Paper 107 at 32) and the panel declined to modify the decision on rehearing. (Decision on Rehearing, Paper 127 at 5). Thus we do not consider Ruelle's arguments.

As we conclude that Scarlato was the first to conceive and reduce to practice an invention of the Count, Ruelle could not have been prior to Scarlato under 35 USC 102(g).

The Ruelle motion for judgment based on priority (Paper 130) is DENIED.

V. Order

It is

ORDERED that the Scarlato Motion for judgment based on priority of invention (Paper 135) is GRANTED;

FURTHER ORDERED that Ruelle Motion for judgment based on priority of invention (Paper 130) is DENIED; and

FURTHER ORDERED that judgment shall be entered against Ruelle in a separate paper.

cc (via email):

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